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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,350	02/18/2004	Wisam Breeji	EYE-011	9204
40336	7590	10/06/2005	EXAMINER	
EYETECH PHARMACEUTICALS, INC. 3 TIMES SQUARE 12TH FLOOR NEW YORK, NY 10036			CRAIG, PAULA L	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/781,350

Applicant(s)

BREEGI ET AL.

Examiner

Paula L. Craig

Art Unit

3761

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-18 and 24-26, drawn to a device for delivery of a therapeutic agent to a treatment site, classified in class 604, subclass 891.1.
  - II. Claims 19-23, 44-48, 50-55, and 68, drawn to a therapeutic agent, classified in class 514, subclass 1.
  - III. Claims 27-37, drawn to a syringe, classified in class 604, subclass 187.
  - IV. Claims 38-43, drawn to a method of injecting or withdrawing fluid from a closed system, classified in class 604, subclass 93.01.
  - V. Claims 49 and 59-67, drawn to a method of treating an ocular disease state in a mammal, classified in class 604, subclass 521.
  - VI. Claims 56-58, drawn to a pharmaceutically acceptable carrier for sustained release, classified in class 424, subclass 457.
2. The inventions are distinct, each from the other because:
3. Inventions I and II, I and III, II and III, and I and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed. The device, the

therapeutic agent, the syringe, and the sustained release carrier each have separate utility.

4. Inventions II and VI are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the therapeutic agent and the sustained release carrier have separate utility in treating disease or injury and in formulating drug preparations. See MPEP § 806.05(d).

5. Inventions I and V, II and IV, II and V, III and IV, and VI and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the device, the therapeutic agent, the syringe, and the carrier as claimed each could be used for other purposes than treating ocular disease states or for injection and withdrawal of fluid from the claimed system.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required differs for each Group, restriction for examination purposes as indicated is proper.

7. Claim 1 is generic to a plurality of disclosed patentably distinct species of the claimed invention, comprising:

**Species A: a device having a membrane as a pressure equalization element** as generically disclosed in Claim 1 and exemplified by specie of Claim 2.

**Species B: a device having a channel as a pressure equalization element** as generically disclosed in Claim 1 and exemplified by specie of Claim 3.

**Species C: a device having an injection port comprised of first and second septa** as generically disclosed in Claim 1 and exemplified by specie of Claim 11.

**Species D: a device having an injection port comprised of a valve** as generically disclosed in Claim 1 and exemplified by specie of Claim 13.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

**Conclusion**

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571) 272-5964. The examiner can normally be reached on 8:30AM-5:00PM M-F.
12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571)272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paula L Craig  
Examiner  
Art Unit 3761

PLC

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

